

Message Text

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10

ORIGIN HEW-06

INFO OCT-01 ARA-10 EUR-12 EA-10 NEA-10 ISO-00 OES-05 EB-07

COME-00 PA-02 PRS-01 CIAE-00 INR-07 NSAE-00 /071 R

66615

DRAFTED BY DHEW/FDA//JRWEINROTH, M.D.

APPROVED BY OES/SCI/BMP/MBEAUBIEN

DHEW/OIH/MACODDING

EA/J:CDUNKERLEY (INFO)

NEA/ARN:MHMAUGHAN (INFO)

ARA/APU:RCFELDER (INFO)

EUR/NSC-IG:JROUSE (INFO)

----- 082000

R 272202Z MAY 75

FM SECSTATE WASHDC

TO AMEMBASSY BUENOS AIRES

AMEMBASSY BONN

AMEMBASSY ROME

AMEMBASSY TOKYO

AMEMBASSY LISBON

AMEMBASSY MADRID

USINT BAGHDAD

UNCLAS STATE 122928

E.O. 11652:N/A

TAGS: OGEN, ETRD, TBIO, AR, GW, IZ, IT, JA,

PO, SP

SUBJECT: FDA ADVISORY - DEFECTIVE MEDICAL DEVICE.

1. FDA ADVISES THAT THE PRODUCT "MYOCARDIAL LEAD FOR RECHARGEABLE PACEMAKERS" MODEL NOS. BL-652 AND BL-653, ALL SERIAL NUMBERS OF BOTH MODEL NUMBERS: RANGING FROM 100 - 300 AND MAY OR MAY NOT INCLUDE A "C" (WHICH INDICATES A CONSIGNED UNIT) MANUFACTURED BY PACESETTER SYSTEMS INC., 12740 SAN FERNANDO ROAD, SYLMAR, CALIFORNIA 91342 MAY BE DEFECTIVE AND ARE BEING RECALLED BY THE MANUFACTURER. THIS PRODUCT WAS DISTRIBUTED FROM NOV. 19, 1973 UNCLASSIFIED

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THROUGH APRIL 18, 1975.

2. THE PRODUCTS OUTER PACKAGE LABELING READS IN PART:"MY-OCARDIAL LEAD FOR PACESETTER RECHARGEABLE PACEMAKERS##PACE-

SETTER SYSTEMS, INC.##SYLMAR, CALIF###".

3. THE MYOCARDIAL LEADS ARE BEING RECALLED BECAUSE OF FAILURES IN THE ELECTRODE TIPS IN TWO PATIENTS, RESULTING IN THEIR DEATHS. INDEPENDENT LABORATORY TESTING REVEALED THAT THE FAILURES WERE PROBABLY DUE TO FRACTURE OF THE CENTRAL 0.020" DIAMETER WIRE ELECTRODE TIP WITH A CONSEQUENT LOSS OF ELECTRICAL CONTINUITY.

4. AT THIS TIME, DOCTORS MONITORING PATIENTS WITH IMPLANTED LEADS ARE BEING INFORMED OF THE PROBLEM, WITH THE FACT THAT TWO PATIENTS DEATHS HAVE BEEN ATTRIBUTED TO THE PROBLEM, BUT IS NOT ADVISING PHYSICIANS TO EXPLANT IMPLANTED LEADS.

5. POSTS ARE REQUESTED TO CONTACT CONSIGNEES TO DETERMINE IF THEY ARE FAMILIAR WITH THE DETAILS OF THE RECALL AND MAY ALSO WISH TO NOTIFY HOST GOVERNMENT'S APPROPRIATE AGENCY WHICH EXERCISES JURISDICTION OVER SUCH DEVICES.

6. FOREIGN CONSIGNEES (LEADS SOLD TO BUT NOT IMPLANTED) ARE AS FOLLOWS:

CUSTOMER	SERIAL NOS. OF MODELS	
	BL-652	BL-653
ROBERTO GRASSI	217	250
LABORATORIOS PIERRE BARDIN		246
G.D. SEARLE - ARGENTINA S.A.C.I.	143	
LA VALLE 2107		
CASILLA CORREO CENTRAL		
BUENOS AIRES, ARGENTINA		
METRON	137	
D-3015 WENNIGAEN-BREDEHBECK		138
JAHNSTRASSE 11 - POSTFACH	148	
FEDERAL REPUBLIC OF GERMANY		

UNCLASSIFIED

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CO. ME.SA, SPA 258
VIA BORROMEI N. 1 B/8
20123 MILANO, ITALY

MEDICAL YACHIYODA CO. LTD. 294
TANAKA-TAMURACHO BLDG.
NO. 12-15, 2-CHOME, SHINBASHI, MINATO-KU
105 TOKYO, JAPAN

MALTIRADIX S.A.R.L. 266
MR. MENDES PAULO
RUB MARQUEX DE FRONTERIA 111
P.O.BOX 1970

LISBOA 1, PORTUGAL

COMESA	267
MR.JUAN ARAGO	279
DR. BELTRAN BIGORRA, 8	285
VALENCIA, SPAIN	288
	299

FOREIGN CONSIGNEES (LEADS IMPLANTED):

PHYSICIANS	PATIENTS	SERIAL NOS.
	MODEL BL-652	

DR. H. SHAARBOF, FRCP	HASSAN ALWASH	178
3RD MEDICAL UNIT		
BAGDAD, IRAQ		
DR. YOKOYAMA	MASAO KATO	179

TOKYO WOMEN'S MEDICAL COLLEGE	OGOSHI GOUSHI	251
10 KAWARACHO SHINYUHN		
TOKYO, JAPAN		

UNKNOWN PHYSICIAN	UNKNOWN	222
POSSIBLY SOLD OR CONSIGNED TO	UNKNOWN	275
MEDICAL YACHIYADA CO. LTD	UNKNOWN	276
TANAKA-TAMURACHO BLDG.		
HQ. 12-15, 2-CHOME, SHINBASHI, MINATO-KU		
105 TOKYO, JAPAN		
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Message Attributes

Automatic Decaptioning: X
Capture Date: 26 AUG 1999
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 27 MAY 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1975STATE122928
Document Source: ADS
Document Unique ID: 00
Drafter: DHEW/FDA/JRWEINROTH, M.D.
Enclosure: n/a
Executive Order: N/A
Errors: n/a
Film Number: D750185-0802
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1975/newtext/t197505104/baaaakwk.tel
Line Count: 144
Locator: TEXT ON-LINE, TEXT ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 3
Previous Channel Indicators:
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Review Action: RELEASED, APPROVED
Review Authority: CunninFX
Review Comment: n/a
Review Content Flags:
Review Date: 29 JUL 2003
Review Event:
Review Exemptions: n/a
Review History: RELEASED <29 JUL 2003 by SilvaL0>; APPROVED <02 FEB 2004 by CunninFX>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
05 JUL 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: <DBA CORRECTED> jms 971010
Subject: n/a
TAGS: ETRD, OGEN, TBIO, AR, GE, IT, IZ, JA, US, PACESETTER SYSTEMS INC
To: BUENOS AIRES
BONN
ROME
TOKYO
LISBON
MADRID

BAGHDAD

Type: TE

Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 05 JUL 2006